



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,117	10/13/2005	Francois-Xavier Berthet	B45315	8407
23347	7590	02/23/2011		
GLAXOSMITHKLINE			EXAMINER	
GLOBAL PATENTS			NAVARRO, ALBERT MARK	
FIVE MOORE DR., PO BOX 13398				
MAIL STOP: C.2111F			ART UNIT	PAPER NUMBER
RESEARCH TRIANGLE PARK, NC 27709-3398			1645	
			NOTIFICATION DATE	DELIVERY MODE
			02/23/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USCIPRTP@GSK.COM  
ELAINE.X.MARTENS@GSK.COM  
PATRICIA.T.WILSON@GSK.COM

<b>Office Action Summary</b>	<b>Application No.</b> 10/523,117	<b>Applicant(s)</b> BERTHET ET AL.
	<b>Examiner</b> Mark Navarro	<b>Art Unit</b> 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 07 October 2010.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) See Continuation Sheet is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_ is/are allowed.  
 6) Claim(s) See Continuation Sheet is/are rejected.  
 7) Claim(s) \_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-946)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
     Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
     Paper No(s)/Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

Continuation of Disposition of Claims: Claims pending in the application are 3-7,9,10,20,22,45,50-52,54-60,82,83,85,87,88,90,96,98,114,115,117,118,120,121,123-126,128-130 and 132-142.

Continuation of Disposition of Claims: Claims rejected are 3-7,9,10,20,22,45,50-52,54-60,82,83,85,87,88,90,96,98,114,115,117,118,120,121,123-126,128-130 and 132-142.

### **DETAILED ACTION**

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 9, 2010 has been entered.

Claims 1-2, 8, 11-19, 21, 23-44, 46-49, 53, 61-81, 84, 86, 89, 91-95, 97, 99-113, 116, 119, 122, 127, and 131 have been cancelled. Accordingly, claims 3-7, 9-10, 20, 22, 45, 50-52, 54-60, 82-83, 85, 87-88, 90, 96, 98, 114-115, 117-118, 120-121, 123-126, 128-130, and 132-142 are pending in the instant application.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. The rejection of claims 3-7, 9-10, 20, 22, 45, 50-52, 54-60, 82-83, 85, 87-88, 90, 96, 98, 114-115, 117-118, 120-121, 123-126, 128-130, and 132-142 under 35 U.S.C.

Art Unit: 1645

102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Berthet et al is maintained.

Applicants are asserting that claims 117, 120 and 123 (from which all other claims depend) are directed to immunogenic compositions comprising at least 3 different antigens selected from at least 3 different categories of Neisserial antigens, and that the claims have been amended to no longer contain overlap among the different classes of antigens. Applicants further assert that Berthet teaches a large genus of possible antigen combinations, in fact claim 15 of Berthet encompasses 7980 possible combinations containing three different antigens.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants assert that claims 117, 120 and 123 (from which all other claims depend) are directed to immunogenic compositions comprising at least 3 different antigens selected from at least 3 different categories of Neisserial antigens. However, Applicants arguments are not commensurate in scope with Applicants claim language. For example, claim 117 recites "comprising at least one Neisserial autotransporter antigen, at least one Neisserial adhesin antigen and at least one different antigen..." The autotransporter antigens are selected from Hsf, Hap, IgA protease, AspA and NadA. The Neisserial adhesion antigen is selected from FhaB, NspA, PilC, Hsf, Hap, MafA, MafB, Omp26, NMB0315, NMB0995, NMB1119 and NadA. The one different antigen is selected from an extensive list of 31 distinct molecules. Applicants attention is directed to the fact that the list of autotransporter antigens and adhesion antigens

Art Unit: 1645

contains significant overlap. For example Hsf, Hap and NadA are listed as both autotransporters and adhesion antigens. Consequently, the presence of any of Hsf, Hap, or NadA in a composition would meet the limitations of "containing at least one Neisserial autotransporter antigen and at least one Neisserial adhesion antigen." There is no claim limitation, and indeed the claim language would directly refute the assertion that the Neisserial Autotransporter antigen and Neisserial adhesion antigen must be different.

Finally, Applicants assert that Berthet teaches a large genus of possible antigen combinations, in fact claim 15 of Berthet teaches of 21 different antigens and encompasses 7980 possible combinations containing three different antigens. Applicants appear to believe that their own claims are somehow a narrow species. Applicants will hopefully appreciate that while Berthet teaches 21 antigens which can be upregulated, Applicants instant claims recites a total of 48 antigens (claim 117) from which 3 (as alleged; or possibly 2 as read by the Examiner) are selected. Applicants instant claims are in fact a much larger genus than the disclosure of Berthet et al. Accordingly, Applicants arguments are not persuasive.

Furthermore, claims 120 and 123 are likewise completely encompassed by the disclosure of Berthet et al. Claim 15 of Berthet et al specifically recites up regulating "one or more" of Hap, TbpA and PorB. (Claim 120 of the instant invention). Claim 15 also upregulates Hap, TbpA and lipo28. (Claim 123 of the instant invention). By upregulating each and every gene recited in the Markush group of claim 15 of Berthet et al (as encompassed by the recitation of "one **or more**") one would arrive at the identical

composition as instantly claimed. (Emphasis added).

The claims are directed to an immunogenic composition comprising at least one Neisserial autotransporter antigen, at least one Neisserial adhesion antigen and at least one different antigen, wherein each of said antigens is isolated or enriched, and wherein the at least one different antigen is selected from Neisserial toxin antigens, Neisserial Iron acquisition proteins and Neisserial membrane associated proteins.

Berthet et al (WO 2001/009350) disclose of immunogenic compositions comprising Nesisserial enriched antigens Hap, TbpA, PorB and lipo28. (See abstract and claims; specifically claim 15).

Given that Hap is a Neisserial autotransporter antigen and a Neisserial adhesion antigen (See claim 117 of instant specification) and that lipo28 is a Neisserial membrane associated protein, the disclosure of Berthet et al is deemed to anticipate the instantly filed claims.

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

***Double Patenting***

3. The rejection of claims 3-7, 9-10, 20, 22, 45, 50-52, 54-60, 82-83, 85-88, 90, 96, 98, 114-115, 117-118, 120-121, 123-126, 128-130, and 132 as being unpatentable over claims 1-57 and 60-71 of copending Application No. 10/523,114 is withdrawn in view of Applicants amendments.

Art Unit: 1645

4. The rejection of claims 3-7, 9-10, 20, 22, 45, 50-52, 54-60, 82-83, 85-88, 90, 96, 98, 114-115, 117-118, 120-121, 123-126, 128-130, and 132 as being unpatentable over claims 1-8, 14-20, 53, and 59-60 of copending Application No. 10/523,044 is withdrawn in view of Applicants amendments.

All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

Art Unit: 1645

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Navarro/  
Primary Examiner, Art Unit 1645  
February 17, 2011